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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,875	02/25/2004	Gary J. Latham	AMBI:089US	1898

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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,875	LATHAM ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-84 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-84 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 25 February 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

NON-FINAL ACTION

1. **Claim(s) 1-84** as originally filed 25 FEB 04 is/are pending in this application.

INFORMATION DISCLOSURE STATEMENT

2. The information disclosure statement (IDS) submitted on 13 OCT 05 contains only page 1 of 7 of Form -1449. Pages 2 of 7 through 7 of 7 of Form-1449 are missing. Please correct.

35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> or
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

5. Claim(s) 1-9, 30, 35-36, 53-54, 56, 83 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Devaux et al. (1987).

Devaux et al. teach a method as recited in Claim 1. In addition, Devaux et al. teach a solution comprising a first and a second nuclease inhibitor. Please note that Devaux et al. teach five monoclonal antibodies (first, second, third, fourth, and fifth nuclease inhibitors) which inhibited the enzymatic degardation of DNA by *Staphylococcus aureus* nuclease to varying degrees. However, when mixed together the five Mabs were able to completely block the enzymatic degardation of DNA by Staphylococcus aureus nuclease.

Regarding the limitation(s) recited in Claim 2 note Devaux et al. teach a method comprising all of the limitations recited in Claim 2 except Devaux et al. do not explicitly teach forming a nuclease inhibitor cocktail prior to mixing the cocktail with the composition. However, the examiner asserts that this limitation is inherent to Devaux et al. See, at least, for example, that portion of Devaux et al. beginning on p.118 entitled "Antibody-mediated nuclease inactivation assay."

Regarding the limitation(s) recited in Claim 54, see, at least, for example, that portion of Devaux et al. beginning on p.118 entitled "Antibody-mediated nuclease inactivation assay."

Regarding the limitation(s) recited in Claim 57-59, 64 and 72-73, see, at least, for example, Column 1 , p.118 of Devaux et al.

6. **Claim(s) 1-12, 15-20, 26-27 and 83** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. [Section 11-1 and 11-2 (1986)].

Davis et al. teach an RNA extraction method, Section 11-1, which utilizes first (guanidine isothiocyanate) and second nuclease inhibitors (β-mercaptoethanol). Davis et al. teach a solution (i.e. the GIT buffer) comprising at least a first and a second nuclease inhibitor.

Davis et al. teach an RNA extraction method, Section 11-2, which utilizes first (vanadyl ribonuclease complex) and second nuclease inhibitors (e.g. heparin, EDTA, SDS, phenol, chloroform). Davis et al. teach a solution (i.e. the homogenization buffer) comprising at least a first and a second nuclease inhibitor.

7. **Claim(s) 1-10, 12, 17-18, 30-31, 42-44, 82-83** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al. [US 5,470,971 (1995)].

Kondo et al. teach a method of performing reverse transcription which comprises obtaining a composition which composition comprises first (Rnasin) and second (DTT) nuclease inhibitors. See at least for example Column 28, beginning at about line 53.

35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim Rejections under 35 USC § 103

10. **Claim(s) 84** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. [Section 11-2 (1986)] in view of the Stratagene Catalog (1988).

Davis et al. teach a method of RNA isolation which utilizes all of the components of the kit recited in Claim 84. Davis et al. do not teach a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition, the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the method taught by Davis et al. wherein the reagents necessary to perform their method are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

Non-Statutory Obviousness-type Double Patenting Rejection

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. **Claim 1-82** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-49 of U.S. Patent No. 6,664,379 (2003). Although the conflicting claims are not identical, they are not patentably distinct from each other. The broad scope encompassed by Claims 1-82 fall within the scope encompassed by Claims 1-49 of U.S. Patent No. 6,664,379 (2003).

13. **Claim 84** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 30 of U.S. Patent No. 6,664,379 (2003) in view of the Stratagene Catalog (1988).

Claim 30 of U.S. Patent No. 6,664,379 teach all of the limitations of Claim 84 of the instant application except Claim 30 does not teach a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition, the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the method recited in Claim 30 of U.S. Patent No. 6,664,379 with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method recited in Claim 30 of U.S. Patent No. 6,664,379 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

14. **Claim 1-82** is/are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 51-79 of copending Application No. 10/675,860. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. **Claim 84** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 56 of U.S. Patent application No. No. 10/675,860 in view of the Stratagene Catalog (1988).

Claim 56 of U.S. Patent application No. 10/675,860 teach all of the limitations of Claim 84 of the instant application except Claim 56 does not teach a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition, the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the method recited in Claim 56 of U.S. Patent application No. 10/675,860 with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method recited in Claim 56 of U.S. Patent application No. 10/675,860 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

CONCLUSION

16. **Claim(s) 1-84** is/are rejected and/or objected to for the reason(s) set forth above.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571).272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The Central Fax number for the USPTO is (571) 273-8300. Before faxing any papers, please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHAN WHISENANT
PRIMARY EXAMINER
Art Unit 1634